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Joseph A. Trautwein, Esq.
Joseph A. Trautwein & Associates
1777 Sentry Parkway West
Blue Bell, PA 19422-2210
Tel: (215) 764-2301
Email: jtrautwein@cpmiteam.com
Attorneys for Plaintiffs-Relators

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSLYVANIA

UNITED STATES OF AMERICA, *ex rel.* [UNDER SEAL], **Plaintiffs,** **v.** **[UNDER SEAL],** **Defendants.**	**Civil Action No.** 16 5209 **COMPLAINT AND JURY DEMAND** **Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)**

FILED UNDER SEAL

NOT TO BE FILED ON PACER

Joseph A. Trautwein, Esq.
Joseph A. Trautwein & Associates
1777 Sentry Parkway West
Blue Bell, PA 19422-2210
Tel: (215) 764-2301
Email: jtrautwein@cpmiteam.com
Attorneys for Plaintiffs-Relators

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSLYVANIA

16-5203

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, CITY OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, and STATE OF WISCONSIN, *ex rel.* SAPF LLC and BRIAN BROUSSEAU,

Plaintiffs,

v.

AMGEN LLC, ASHFIELD HEALTHCARE LLC, UDG HEALTHCARE, ACCREDO SPECIALTY PHARMACY, EXPRESS SCRIPTS HOLDING COMPANY, UNITEDBIOSOURCE CORPORATION, MCKESSON CORPORATION, INVENTIV HEALTH INC., AND THE LASH GROUP,

Defendants.

Civil Action No.

COMPLAINT
AND JURY DEMAND

Filed Under Seal Pursuant to
31 U.S.C. § 3730(b)(2)

PRELIMINARY STATEMENT

1. Plaintiffs-Relators Brian Brousseau and SAPF LLC, through their undersigned attorneys, allege, based upon personal knowledge, relevant documents, investigations and information and belief, as follows: This is a civil action brought against defendants Amgen LLC ("Amgen"), Ashfield, Accredo and United BioSource Corporation. ("Ashfield, Accredo and UBC") and the McKesson, inVentiv and Lash Group ("McKesson, inVentiv and Lash") under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA"), and analogous state false claims laws to recover treble damages sustained by, and civil penalties and restitution owed to, the United States Government and the respective state governments as a result of two intertwined, unlawful drug marketing schemes.

2. First, from 2006 up and through the present, Amgen has paid tens of millions of dollars to Ashfield, Accredo and UBC to employ clinicians (i.e., Nurse Educators) to recommend Amgen's disease drugs to both providers and patients under the guise of education and counseling — a variation on a scheme the Office of the Inspector General (the "OIG") refers to with repudiation as "white coat marketing." Second, also since 2006, Amgen, McKesson, inVentiv and Lash, and Ashfield, Accredo and UBC clinicians have provided remuneration in the form of free services to prescribing providers in order to induce those providers to recommend Amgen Covered Drugs to patients—a more typical unlawful "quid pro quo" kickback scheme. As a result of these schemes, pharmacies have and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements. These schemes are ongoing.

3. Defendants' scheme undermine the independent decision making of providers, an important element in Government Healthcare Program coverage policy. The providers

prescribing Amgen Covered Drugs did not necessarily do so because they believed, based on their review of peer-reviewed medical literature or discussion with their colleagues, that the drugs would help their patients. Rather, Amgen's Covered Drugs were and are often supplied because Defendants actively and improperly pursued and enticed providers with free services and other forms of remuneration.

4. As a result of these schemes, pharmacies have and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the claims Relators bring on behalf of the United States under the FCA pursuant to 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over the claims asserted under the laws of the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New York, the City of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State of Wisconsin, pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 37372(b).

6. This Court may exercise personal jurisdiction over Amgen, Ashfield, Accredo and UBC and McKesson, inVentiv and Lash and venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and 1391(c) because Amgen, Ashfield,

Accredo and UBC, and McKesson, inVentiv and Lash each transact business in this District and, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District

7. Relators have direct and independent knowledge on which the allegations herein are based, are original sources of this information and have voluntarily provided the information to the United States before filing this action based on the information. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relators, each is an original source under 31 U.S.C. § 3730(e)(4) and the applicable provisions of the respective State False Claims Act laws.

PARTIES

8. Relator Brian Brousseau was employed by Amgen from February of 2004 until December of 2014 in the Compliance and Marketing Departments.

9. Relator SAPF LLC is a New Jersey-based entity organized under the laws of the State of Delaware and formed to investigate and act as co-relator the matters alleged herein.

10. Co-Relators bring this action on behalf of the United States pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 et seq.

11. Defendant Amgen Inc. ("Amgen"), a Fortune 500 company, is a publicly-traded diversified, human therapeutics company in the biotechnology industry. It conducts business throughout the United States (including Pennsylvania) and in many other countries. Its principal place of business is Thousand Oaks, California. Amgen engages in the discovery, development, manufacture, and delivery of bio-therapeutics (e.g., prescription drugs) for various medical needs. Those drugs included Enbrel (etanercept); 2) Repatha (evolocumab);Nuelasta; NPlate;

Vectibix; Xgeva; Imlygic; Krypolis; Aranesp' Sensipar; and, 3) Prolia (denosumab). ("Covered Drugs").

12. Defendant Pfizer, a Delaware Corporation is a multinational pharmaceutical company. It conducts business throughout the United States (including Pennsylvania) and in many other countries. From 2002 to October 31, 2013 Pfizer co-promoted Enbrel along with Amgen and would be liable for any unlawful promotion up to that time.

13. Defendant, Ashfield Healthcare LLC ("Ashfield") whose U.S. headquarters is in Ivyland, PA. Ashfield is a subsidiary of UDG Healthcare plc ("UDG"), an Ireland based company. Defendant Ashfield is the world's largest provider of biopharmaceutical development and commercial outsourcing services to healthcare sector businesses, including Amgen.

14. Defendant Accredo Specialty Pharmacy ("Accredo"). Accredo is currently a wholly owned subsidiary of Express Scripts Holding Company ("Express"). Express is a Delaware Corporation headquartered in St. Louis, MO,

15. Defendant United BioSource Corporation ("UBC") is another subsidiary of Express.

16. Defendant McKesson Corporation ("McKesson") is Delaware Corporation whose corporate headquarters are in San Francisco, California.

17. Defendant, inVentiv Health Inc., ("InVentiv") whose headquarters are in Burlington, MA.

18. Defendant, Lash Group ("Lash"), a subsidiary of AmeriSource Bergen ("Amerisource"). Lash is headquarted in Fort Mill, S.C. Amerisource is a Delaware Corporation whose corporate headquarters are in Chesterbrook, PA.

19. Defendants Amgen, Ashfield, Accredo, UBC, McKesson, inVentiv, Lash and Amerisource are collectively referred to as "Defendants" unless noted otherwise herein.

STATUTORY BACKGROUND

A. The False Claims Act

20. The FCA establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

31 U.S.C. § 3729(a)(1)(A)-(C). Within the meaning of the FCA, "knowing" is defined to include reckless disregard and deliberate indifference. *Id.*

21. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim ranging from $5,500 to 11,000. *See, e.g.,* 64 Fed. Reg. 47099, 47103 (1999).

B. The Anti-Kickback Statute

22. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b *et seq.* ("AKS"), states as follows in relevant part:

> (b) Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part

> under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

23. For purposes of the AKS, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

24. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

25. In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and

other federal laws governing the provision of health care services in the United States.

26. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the Anti-Kickback Statute are also a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h).

27. Knowingly providing kickbacks to providers to induce them to prescribe a drug (or to influence provider prescriptions) for individuals who seek reimbursement for the drug from a federal Government healthcare program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

28. The Balanced Budget Act of 1997 amended the AKS to include administrative civil penalties of $50,000 for each violation, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).

29. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Defendants from liability for the conduct alleged herein. Compliance with the AKS is a condition of payment under federal health care programs.

AFFECTED HEALTH PROGRAMS

30. For the drugs at issue in this case, generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

31. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

A. Medicare

32. Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395, *et seq.* ("Medicare Program"). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006. All persons enrolled in Medicare Part A and\or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. The United States Department of Health and Human Services ("HHS"), through its component agency, the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

33. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the

beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

34. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information ...necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

35. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has

actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R.§ 423.336.

36. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R.§ 423.315(a).

37. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

38. By statute, all contracts between a Part D Plan sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

39. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.P.R.§ 423.505(h)(l).

40. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present

include a provision in which the sponsor "agrees to comply with ... federal laws and regulations designed to prevent ... fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729, et seq.), and the anti-kickback statute (§ 1127B(b) of the Act)."

41. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

42. A Part D Plan sponsor also is required by federal regulation to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment", provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that

> this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under§ 423.87l(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k).

43. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.

44. In accordance with this regulatory requirement, since the Part D program began, Medicare has required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best

> knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

45. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

46. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

47. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physician to be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me ... The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity

B. Medicaid

48. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State

Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

49. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended ... as medical assistance under the State plan." 42U.S.C. § 1396b(a)(l).

50. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.P.R.§ 430.30.

51. Claims arising from illegal kickbacks are not authorized to be paid under state

regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

52. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

53. For example, in New York, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished, [...]will be subject to the following certification .... I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

C. TRICARE

54. TRICARE (formerly known as CHAMPUS), is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their\dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option

benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

55. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In-addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

56. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

57. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE DoD/CHAMPUS Medical Claim -- Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

58. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program as well. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensing reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. DLA bills TRICARE directly for drug replenishment costs.

59. Pursuant to 38 U.S. C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at

least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

60. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

61. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

62. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R.§ 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

D. Veterans Administration Health Care

63. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

64. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS") program. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as 26% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). AVA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor ("PPV") for distribution of pharmaceuticals. Since May 10, 2004, McKesson Corporation has served as the VA's PPV. The PPV fills the order for the facility, and then submits an invoice to the VA for payment, charging the VA the price set by the contract awarded by the VA to the drug manufacturer. The VA makes payment to the PPV. The PPV then seeks a chargeback from the drug manufacturer for any difference between the contract price paid by the VA and the PPV' s acquisition price.

65. Pursuant to the PPACA, among other things, all claims to Government reimbursed programs resulting from a violation of the AKS are also a violation of the FCA.

66. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE and Veterans Administration Health Care, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed. The claims submitted here, violated the AKS in that these claims stemmed from prescriptions written by providers in exchange for bribes knowing that claims for reimbursement would be submitted to the above programs as a result. As such, and as more fully discussed below, the prescribing healthcare providers expressly and impliedly falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE and Veterans Administration Health Care.

67. In addition to falsely certifying compliance with the AKS, the healthcare providers referred to herein also falsely certified compliance with contractual provisions that were conditions for payment.

68. As detailed herein, Amgen and Pfizer devised and implemented schemes whereby it gave kickbacks to third party "educators" from Ashfield, Accredo and UBC to recommend that providers prescribe the Covered Drugs and whereby Defendants provided free, in-kind services to providers to induce those providers to prescribe the Covered Drugs.

69. Knowingly paying kickbacks to induce physicians to prescribe a drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a federal Government health program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar state False Claims Acts.

DEFENDANTS' FRAUDULENT SCHEMES

70. In this matter, Ashfield, Accredo,UBC (and other unnamed co-conspirators) contracted to provide Amgen a force of Nurse Educators work with Amgen's sales force to promote Amgen's Covered Drugs Nurse Educators are health care professionals who possess training, knowledge and experience in disease management, pre-disease care, and disease prevention. A Nurse Educator certification is "practice based" and requires health care professionals to gain professional experience working in the field.

71. Certified Nurse Educators are recognized as specialty clinicians with particular training, education and experience in disease education and care. Not surprisingly, Nurse Educators are in particular demand for providers who care for disease patients. Many Nurse Educators are employed by primary care and specialty practices to work with disease patients. As clinicians with significant training, education and experience, Nurse Educators can command significant compensation in the healthcare workforce.

72. In this matter, Amgen and Pfizer paid Ashfield, Accredo, UBC (and others) to unlawfully promote its Covered Drugs using Nurse Educators.

A. Defendants' Unlawful "White Coat" Marketing

73. Amgen realized that its potential prescribers were frequently refusing to meet with its drug reps about Amgen's disease drug sales.

74. As is detailed below, Amgen sought to overcome these barriers by using an unlawful marketing scheme through its relationship with Ashfield, Accredo and UBC.

75. Over the last decade, Amgen entered into a relationship with Ashfield, Accredo and UBC (and others) whereby Ashfield, Accredo and UBC would use Nurse Educators to gain access to providers in order to market Amgen's Covered Drugs.

76. Amgen believed that, as expert clinicians, Ashfield, Accredo and UBC Nurse Educators were more likely than drug reps to gain access to providers because Nurse Educators would be able to talk on a "peer to peer" level with providers regarding disease.

77. Relators confirm that Nurse Educators were viewed by providers as more credentialed and thus more credible than Amgen's drug reps. Amgen paid Ashfield, Accredo and UBC tens of millions of dollars for the Nurse Educators force. Each of the Ashfield, Accredo and UBC Nurse Educators underwent a rigorous Amgen training program and learned sales techniques – similar to the program each Amgen drug rep undergoes.

78. Once trained, Amgen started to deploy Ashfield, Accredo and UBC Nurse Educator clinicians across the country to call on disease providers who could prescribe Amgen products.

79. Amgen needed a clever and nuanced approach to disguise this marketing strategy. After all, Amgen knew that Nurse Educators could not openly appear to act in the role of drug reps for several reasons. One, Amgen feared that providers would limit Nurse Educator access in the same manner that drug rep access was being limited. Two, if Amgen openly admitted that Nurse Educators were promoting its drugs, Amgen would be forced to lawfully restrict the Nurse Educators' messaging to only FDA approved marketing materials or risk a charge of "off label" promotion. And, three, the OIG refers to this type of marketing as "white coat" (i.e., utilizing clinicians to promote drugs) as particularly suspect.

80. As a result, Amgen created a contrived disease awareness program that would cover the true role for the Nurse Educators – a program that could make Nurse Educators appear to be functioning distinct and independent from the role of a true drug rep.

81. In doing so, Amgen designated the Nurse Educators as "educators" who, instead

of selling drugs, were now marketing and promoting the free disease educational services to providers.

82. However, despite using a "form-over-substance" labeling of Nurse Educators, witnesses known to Relators all make clear that the Nurse Educators were drug reps by every measure except title.

83. The white coat marketing part of the strategy was hugely successful as Amgen gained the much coveted "access" to providers and patients by using Ashfield, Accredo and UBC' Nurse Educators.

84. After gaining this access under the auspices of an education service, Ashfield, Accredo and UBC Nurse Educators (i.e. "white coated" clinicians recognized as experts in disease treatments) were now also in an ideal position to exclusively recommend Amgen Covered Drugs to providers and, more troubling, directly to patients.

85. Witnesses confirm that Amgen trained and directed Ashfield, Accredo and UBC Nurse Educators to promote directly Amgen's disease drug to providers and patients once Nurse Educators gained access to and were in a position to recommend Amgen Covered Drugs to providers.

86. Since Amgen was paying Ashfield, Accredo and UBC to engage in this conduct, this scheme violates the AKS which makes it unlawful to pay remuneration in exchange for a recommendation of an item paid for by the Government.

87. In this case, Defendants are paying Nurse Educators – medical professionals – to promote Amgen products under the guise of providing providers and patients with "education." The act of paying a non-employee third party white coated clinician to recommend a drugs to providers is not protected under any safe harbor exception and thus this conduct violates the

AKS.

88. Finally, Amgen also violates the AKS by and through the utilization of its Patient's assistance foundation ("PAF") and programs ("PAP").

89. Amgen's PAF and PAP act as a "seeding program" - a scheme that OIG has found violates the AKS because such programs act as inducement to patients to "self-refer" for Amgen's Covered Drugs (e.g., Aranesp (darbepoetin alfa; Blincyto (blinatumomab(; Corlanor (ivabradine); Enbrel (etanercept); Epogen (epoetin alfa); Imlygic (talimogene laherparepvec); KyprolisInjection (carfilzomib);Neulasta (pegfilgrastim);Neupogen (filgrastim); Nplate (romiplostim);Prolia (denosumab); Repatha (evolocumab); Sensipar (cinacalcet HCl); Vectibix (panitumumab); XGEVA (denosumab)

90. Amgen contracts with unnamed co-conspirators to administer the PAP and PAF's and track ROI from the programs.

91. Although Amgen purports to set appropriate eligibility criteria and guidelines, these guidelines are manipulated and ignored in order to initially provide Covered Drugs for free as an inducement to self-refer – only to change the criteria or guidelines in order to the Covered Drug under a patient's reimbursable benefits.

92. This scheme includes mandating that a patient apply for various Government reimbursed Drug coverage (e.g., Medicaid, LIS, Medicare, etc) so as cause a the patient- who has initially been induced because of the "Free" or reduced cost drug to then have that drug reimbursed by government payers.

B. *Quid Pro Quo* 1—Free Clinicians for Referrals

93. In addition to the white coat marketing scheme, Amgen, in a separate but related

more traditional kickback scheme, also sought to incentivize disease care providers to choose Amgen Covered Drugs over competitors' drugs. Here, Amgen identified the unique and particular needs and challenges that disease care providers faced in managing their own practices and patients. Once these providers' needs and challenges were identified, Amgen, through Ashfield, Accredo and UBC began selling these providers "solutions" to those needs and challenges.

94. Specifically, Amgen began offering and then providing these providers the time, service and expertise of a Ashfield, Accredo and UBC employed Nurse Educator both to help manage that providers' disease patients and to provide disease training to the providers' staff. Of course, in typical *quid pro quo* fashion, in order to be given these services those providers would have to "support" (i.e., write prescriptions for) Amgen's disease drugs.

95. Once trained and deployed, these Nurse Educators began to provide free education services to any provider who would prescribe Amgen's products. The Ashfield, Accredo and UBC Nurse Educators were successful in saving prescribers' time, money and resources and, in many instances, resulted in receiving higher reimbursement rates associated with certain disease care metrics. Not surprisingly, Amgen also saw its drugs sales increase each time a Nurse Educator was deployed.

96. Amgen providing educational and other services to providers in exchange for recommending its drug, also violates the anti-kickback statute.

C. *Quid Pro Quo* 2—Free Reimbursement Experts for Referrals

97. Amgen also induced providers to recommend its drugs by offering and providing what is referred to as "reimbursement support" ("RS") services through the McKesson, inVentiv and Lash Group.

98. For the last half a decade, Amgen drug reps' pitch to providers in this regard has essentially been as follows:

> *Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable.*

99. This value proposition was a powerful tool in the hands of Amgen's drug reps and used to influence providers to recommend Amgen Covered Drugs. Amgen's drug reps could offer a provider an "on call" reimbursement support team to manage the patient's Amgen drug prescriptions. RS services became very much a part of the Amgen drug reps' collective sales pitch.

100. That is, rather than promoting and marketing its drugs based on patient outcomes and efficacy, Amgen introduced an additional incentive to providers to recommend its drugs to patients. Amgen knew that this service would present a tangible value to the providers. When that offer was accepted, the provider received the benefits of the RS service without actually having to pay for those services.

101. Most importantly, these services resulted in greater profit from each provider's E/M unit charge. It was in this fashion, giving a provider free RS services, that Amgen "eliminate[d] an expense that [the provider] would have otherwise incurred"[1] if the provider would have had to perform the tasks associated with the Amgen drug prescription. Such "in kind" remuneration given to induce a recommendation for an Amgen drug is an unlawful

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[1] Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) ("CPG") Section II (2), such service is a suspect remuneration as it "eliminate[d] an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)".

kickback under the AKS.

102. Amgen's RS services were offered through another contractual partner: McKesson, inVentiv and Lash Group ("McKesson, inVentiv and Lash"). Lash is a subsidiary of AmeriSource Bergen. Amgen pays McKesson, inVentiv and Lash millions of dollars each year to manage their free RS service offerings.

103. Within the pharmaceutical industry, McKesson, inVentiv and Lash openly promote the nature of the services they offer to pharmaceutical companies and that their services will increase a pharmaceutical company's drug sales. According to McKesson's website, "[its] Reimbursement and Access Services Solution Center offers single gateway programs for reimbursement hotlines, patient assistance programs, [...] and other healthcare customer support services on behalf of manufacturers."[2]

104. Further, according to Lash's website,[3] it boasts about its RS Services and their value to providers: "Our dedicated site coordinators strive to become *an extension of the provider's team*, with a single point-of-contact case management approach that streamlines and optimizes reimbursement processes. Working closely with your field teams, our site coordinators *develop strong relationships with practices and establish regional expertise around payer trends.*"[4] (emphasis added). Here, Amgen utilized Lash to provide unlawful RS services for Prolia.

105. Here, Amgen, through McKesson, inVentiv and Lash, gave providers an *a la carte* single point of contact person to manage the Amgen prescription process – which greatly

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[2] McKesson Healthcare Services, http://www.mckesson.com/manufacturers/pharmaceuticals/oncology-and-specialty-pharmaceutical-services/reimbursement-and-access-services-solution-center/ (last visited June 20, 2016)
[3] Amerisource Annual Report, http://www.sec.gov/Archives/edgar/data/1140859/000104746915008939/a2226704z10k.htm (last visited June 20, 2016)
[4] Lash Reimbursement, http://www.lashgroup.com/services/reimbursement (last visited June 7, 2016)